

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

KOLOSSOV *et al.*

Appl. No.: 10/594,188

§ 371 Date: June 21, 2007

For: **Novel Method for the Preparation
of Embryoid Bodies (EBs) and Uses
Thereof**

Confirmation No.: 7273

Art Unit: 1632

Examiner: CHEN, Shin Lin

Atty. Docket: 2590.0040002/EJH/SAC

Reply to Restriction Requirement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated October 16, 2008, Applicants hereby provisionally elect to prosecute Group X, represented by claims 1-33, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are cardiomyocytes and are genetically engineered. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made **with traverse**.

Applicants respectfully assert that this Restriction Requirement based on lack of unity of invention is unfounded. According to 37 C.F.R. § 1.475(a), "a national stage application shall relate to one invention only *or to a group of inventions so linked as to form a single general inventive concept*." *Id.* (emphasis added). The Manual of Patent Examining Procedure (M.P.E.P.) provides the following guidance regarding "a single general inventive concept:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

M.P.E.P. § 1893.03(d) (Rev.6, Sept. 2007) at 1800-208; *see also*, 37 C.F.R. § 1.475(a).

The Examiner asserts that the claims of Groups I-XXI allegedly do not share a corresponding special technical feature as the technical feature in claim 1 is not special in view of U.S. Patent No. 6,602,711(Thomson *et al.*) (hereinafter "the '711 patent") or Published U.S. Appl. No. 20020146678 A1 (Benvenisty) (hereinafter "the '678 application"). *See* Office Action at page 4. Applicants respectfully disagree.

In the present case, a corresponding special technical feature that is common to Groups I-XXI is the use of **agitation techniques for culturing multi- or pluripotent cells** for the generation of cell aggregates in high density and high quality. This feature is present in all of the pending claims, and therefore links the claims as a single general inventive concept under PCT Rule 13.1. As such, the claims in Groups I-XXI should be grouped and examined together.

Contrary to the Examiner's assertion, the '711 patent does not disclose this corresponding special technical feature. Rather, the '711 patent describes the generation of embryonic stem (ES) cell aggregates by partially dissociating overgrown or piled cultures of ES cells into clumps. These cells are then cultured in suspension to induce further differentiation. To avoid adhesion to the surface of the cell culture dish, incubation on a rocking table or a non-adherent plastic dish is suggested. Clearly, the method described in the '711 patent uses the rocking table not for generation of

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aggregates themselves, but rather only to prevent the already existing aggregates from sticking to the surface during culture.

Similarly, the '678 application does not disclose this corresponding special technical feature. The '678 application describes a method for obtaining differentiated cells. However, the '678 application does not discuss the use of agitation as a way of generating cell aggregates in high density and high quality. Thus, Applicants respectfully submit that the '711 patent and the '678 application do not disclose the corresponding special technical feature common to Groups I-XXI of the instant application. Accordingly, the claims of Groups I-XXI should be grouped and examined together.

In addition, Applicants respectfully assert that at a minimum, Groups I to X should be rejoined as these claims are all drawn to a method of producing embryoid bodies from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method and a differentiated cell or tissue derived from the embryoid body (EB). The type of cell that the embryoid bodies are differentiated into is the only difference between these groups. As such, Applicants assert that searching and examining these groups together would not be a serious burden on the Examiner as references relevant for each would be found in the same search.

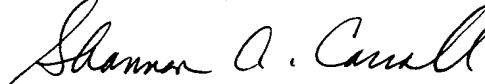
Thus, as indicated above, the '711 patent and the '678 application do not disclose the corresponding special technical feature of Groups I-XXI. Therefore, Applicants believe that the claims in Groups I-XXI should be grouped and examined together. Furthermore, at a minimum Groups I to X should be grouped and examined together as

searching and examining these groups together would not be a serious burden on the Examiner. Accordingly, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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